UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,577	05/26/2005	Andreas Bergmann	2582.009	2150

23405 7590 09/26/2008

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
09/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,577	BERGMANN ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/18/2008 has been entered.

2. Claims 1-12 have been canceled.

Claims 13-17 are pending and currently under examination as they read on a method of for the detecting thyroid stimulating hormone (TSH) receptor autoantibodies in a biological sample.

3. The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Action will be in response to Applicant's Arguments/Remarks, filed 08/18/2008.

The rejections of record can be found in the previous Office Action.

Priority

4. In view of Applicant's amendment, filed 01/28/2008, the domestic priority date for claims 13-17 is deemed the effective filing date of PCT/EP03/12129, i.e., 10/31/2003.

Applicant's claim for foreign priority is acknowledge. However, there does not appear to be a certified translation of the priority document, 10255144.8. Therefore, Examiner cannot determine whether the priority document provides sufficient written support for claims currently under examination, i.e., claims 13-17.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Parmentier et al. (U.S. Patent 6,228,597 B1, reference of record, see entire document) as evidenced by Weir et al. (*Handbook of Experimental Immunology in Four Volumes*, Volume 1: Immunochemistry, Forth Edition, 1986, Blackwell Scientific Publications, Palo Alto, CA, USA, pages 34.7-34.8, reference of record).

Applicant's arguments, filed 08/18/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument that Parmentier et al. do not teach or suggest using naturally occurring autoantibodies that are isolated from Graves' Disease patient sera, the following is noted.

Parmentier et al. clearly teach the same or nearly the same method of detecting TSH receptor autoantibodies in a biological sample. For example, see claim 9 of Parmentier et al. (provided herein for Applicant's convenience):

> Claim 9. Process for the quantitative detection of anti-thyrotropin receptor antibodies (**anti-TSHr**) in a biological sample comprising the steps of:
> contacting a polypeptide according to claim 5 with the **biological sample suspected of containing anti-TSHr antibodies**,
> incubating with labelled TSH, **or with labelled anti-TSHr antibodies**;
> measuring the remaining, bound labelled TSH or bound labelled anti-TSHr antibodies, after competition between the labelled and unlabelled species; and
> correlating results from the measuring step to the presence of anti-TSHr antibodies.

In response to Applicant's argument that the anti-TSHr antibodies taught by Parmentier et al. are not autoantibodies, it is noted that given that Parmentier et al. teach collecting samples from two patients with Grave's disease having high levels of thyroid stimulating immunoglobulins in the circulation, the anti-TSHr antibodies would be human autoantibodies to TSHr because autoantibodies to TSHr is the underlying pathogenesis of Graves' Disease (see paragraph bridging columns 8-9).

Furthermore, Parmentier et al. expressly teach that the anti-TSHr antibody would be purified. In addition, Parmentier teaches the antibody to be labeled with a radioactive isotope (see column 10 lines 6-25) which reads on direct labeling of the antibody as recited in claims 16-17.

Taken together, Parmentier anticipates the present claims. Taken together, one of ordinary skill in the art would have readily understood that Parmentier et al. taught a method of detecting TSH receptor autoantibodies in a biological sample using purified, labeled human autoantibodies to TSHr isolated from Graves' patient sera.

Although Parmentier et al. do not teach that the antibody is obtained by affinity purification, *per se*, given the prior art teaches the same or nearly the same purified anti-TSH receptor autoantibody, under the broadest reasonable interpretation, the same antibody can also be obtained by affinity chromatography. Therefore, Parmentier anticipates the present claims.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 13-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Parmentier et al. (U.S. Patent 6,228,597 B1) in view of Brown et al. (*J. of Clinical Endocrinology and Metabolism*, 1983, 56:156-163, cited in IDS).

Given the absence of a rebuttal to the outstanding rejection of record, it appears that Applicant has acquiesced to the rejection of record. Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 13 **stands** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,228,597. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons stated in the previous Office Actions, mailed 09/17/2007 and 04/16/2008.

Given the absence of a rebuttal to the outstanding rejection of record, it appears that Applicant has acquiesced to the rejection of record. Therefore the rejection stands for the reasons of record.

Conclusion

11. No claim is allowed.

12. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action following the Request for Continued Examination (RCE), filed 08/18/2008, in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
September 23, 2008

/Phillip Gambel/
Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
Art Unit 1644
September 24, 2008